

Notice of Allowability

Application No.

10/629,749

Examiner

Shafiqul Haq

Applicant(s)

LU, NATALIE T.

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to application filed 7/30/03.
2. ☒ The allowed claim(s) is/are 1-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☒ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>6/8/06</u> |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>7/30/03</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input checked="" type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Affidavit or declaration of biological deposit

1. Applicant or Applicant's representative must submit an affidavit or declaration as agreed with Applicants' representative in a telephone interview on June 12, 2006, indicating that the hybridoma cell line (PTA-5096) has been deposited under the terms of Budapest Treaty and will be irrevocably and without restriction or condition released to the public upon the issuance of a patent (MPEP 2410.01 and MPEP 2410.02). Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit, 5 years after the last request for a sample, or for the enforceable life of the patent whichever is longer.

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance: The closest prior arts does not teach or reasonably suggest a monoclonal antibody having specificity for crack cocaine metabolites anhydroecgonine methyl ester and ecgonidine. Prior arts also fail to teach or suggest an immunogen comprising a conjugate of crack cocaine metabolite anhydroecgonine methyl ester and ecgonidine conjugated to an antigenic carrier. Yugawa et al. (US 6,174,723 B1) and Wirsching et al. (WO 97/21451) both disclose immunogens conjugated with cocaine and monoclonal antibody with specificity for cocaine and cocaine derivative. (e.g. norcocaine, ecgonine, methylecgonine and benzoylecgonine. See column 10 of '723 patent). Thrstle discloses polyclonal antibody (antiserum against cocaine) with specificity for

benzoylecgonine and cocaethylene but having substantially less specificity for anhydro ecgonine methyl ester (see cross-reactivity data). However, none of the arts teach or suggest monoclonal antibody having specificity for crack cocaine metabolites anhydroecgonine methyl ester and ecgonidine or an immunoconjugate comprising a conjugate of crack cocaine metabolites anhydroecgonine methyl ester and ecgonidine conjugated to an antigenic carrier.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Examiner's amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
4. Authorization for this examiner's amendment was given in a telephone interview with Jon Tornquist on June 8, 2006
5. Claim 6 has been amended as follows:

In claim 6, line 2, after the phrase "specificity towards a crack cocaine" replace "metabolite" with --metabolites anhydroecgonine methyl ester and ecgonidine--.

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In claim 6, line 3, after the phrase "immunogen comprising a crack cocaine" replace "metabolite" with --metabolites anhydroecgonine methyl ester and ecgonidine--.

6. In claim 11, line 1, after the phrase "immunogen comprising a crack cocaine" replace "metabolite" with --metabolites anhydroecgonine methyl ester and ecgonidine--.

7. In claim 14, line 1, after the phrase "immunogen comprising a crack cocaine" replace "metabolite" with --metabolites anhydroecgonine methyl ester and ecgonidine--.

8. In claim 14, line 1, after the phrase "conjugated to a linker molecule" replace "and" with --which is linked to--.

Conclusion

9. Claims 1-16 are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHARIQUL HAQ
EXAMINER
ART UNIT 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
ART UNIT 1641

06/12/06